UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

Richard Cleveland, Plaintiff, v. ZIMMER, INC.; ZIMMER HOLDINGS, INC.; AND ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC. Defendants.	Court File No. _____ **COMPLAINT - JURY TRIAL DEMAND**

COMES NOW the Plaintiff, Richard Cleveland, by and through his undersigned Counsel, and for his Complaint against the Defendants, alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Richard Cleveland, as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, distribution, and selling of Defendants' knee replacement product, the Zimmer NexGen CR-Flex femoral component and the NexGen MIS Stemmed Tibial component of the Zimmer NexGen total knee replacement system (hereinafter "Zimmer NexGen Knee").

2. Defendants knew or should have known that the Zimmer NexGen Knee can loosen in patients, such as Plaintiff Richard Cleveland, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent revision surgery and/or knee replacement. Further, Defendants misled health care professionals and the public into believing that the Zimmer NexGen Knee was safe

and effective for use in knee replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals to utilize the Zimmer NexGen Knee, even though Defendants knew or should have known that the Zimmer NexGen Knee was unreasonably unsafe; and failed to warn health care professionals and the public about the safety risks of the Zimmer NexGen Knee.

PARTIES

3. Plaintiff Richard Cleveland is a citizen of the State of Illinois, and a resident of Minooka, Illinois.

4. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

5. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

6. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized and existing under the laws of Ohio, and has its principal place of business in Dover, Ohio.

7. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer NexGen Knee. Defendants' products, including the Zimmer NexGen Knee, are sold throughout the world, including within the State of Illinois.

JURISDICTION AND VENUE

8. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

9. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391(a), as a substantial number of the events, actions or omissions giving rise to Plaintiff's claims occurred in this district. At all times material hereto, Defendants conducted substantial business in this district.

FACTUAL BACKGROUND
KNEE REPLACEMENT BACKGROUND

10. Total Knee Arthroplasty ("TKA"), also called total knee replacement, is a common medical procedure performed. The surgery is designed to help relieve pain and improve joint function in people with severe knee degeneration due to arthritis or trauma.

11. Upon information and belief, the TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh bone (femur) and the shin bone (tibia) are removed as is often the underside of the kneecap (patella).

12. Upon information and belief, about 85 to 90 percent of total knee replacements are successful up to ten years.

13. *Mechanical loosening* means that for some reason (other than infection) the attachment between the artificial knee and the bone has become loose.

14. Loosening can occur with any component of the artificial knee: the femoral, the tibial or the patellar component.

15. Upon information and belief, loosening of an artificial knee can be diagnosed using X-ray images that show one or more radiolucent lines around the contours of the artificial knee joint.

16. A loose artificial knee is a problem because it causes pain and wearing away of the bone. A painful loose knee can restrict the patient's daily activities severely. A loose artificial knee also involves severe psychical burden for the patient.

17. Once the pain becomes unbearable or the individual loses function of the knee, another operation may be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

18. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

19. Upon information and belief, a revision operation of a failed knee implant is problematic because the surgeon must reconstruct the severe bone loss caused by bone destruction around the failed total knee prosthesis, and restore the stability in the revised total knee.

20. Upon information and belief, the results of a revision operation are not as good as the first, and the risks of complications are higher. The range of motion in the knee after revision surgery may be reduced and the walking capacity may also be diminished. The rate of loosening increases after revision surgery.

ZIMMER NEXGEN KNEE FACTS

21. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products.

22. The Zimmer NexGen Knee uses a "high-flex" femoral component that purports to allow a greater degree of flexion than the standard femoral component.

23. The Zimmer NexGen Knee also uses a stemmed tibial component that is designed to be assembled within the patient thereby allowing for minimally invasive surgery techniques.

24. The Defendants generally, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of a pharmaceutical, and by said activities, caused the Zimmer NexGen Knee to be placed into the stream of commerce throughout the United States.

25. Defendants made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for the Zimmer NexGen Knee.

26. Upon information and belief, Defendants were in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Zimmer NexGen Knee.

27. Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and

regulations thereof, in conjunction with the approval process, labeling, and other after-market activities that pertain to the Zimmer NexGen Knee.

28. The Zimmer NexGen Knee has been widely advertised, marketed and represented by the Defendants as a safe and effective treatment.

ZIMMER NEXGEN KNEE PROBLEMS

29. Studies show that a knee implant that allows for higher flexation, like the Zimmer NexGen Knee, is more likely to fail because higher flexation places the knee implant at a higher risk of loosening.

30. Additionally, numerous peer-reviewed articles establish that the NexGen CR-Flex fails to provide any statistically significant added flexion or range of motion compared to the standard NexGen CR.

31. In March 2010, Dr. Steven Weeden, of the Texas Hip and Knee Center, presented a study at a national meeting of the American Association of Orthopaedic Surgeons reporting a higher than expected rate of early loosening in cemented primary total knee replacements when a MIS tibial component was used without an additional modular stem. In the MIS tibia components placed without an additional modular stem the failure rate was 24% versus 4.2% with a stem.

32. On or around April 2010, Defendants sent an "Urgent Device Correction" letter to all customers using the MIS Stemmed Tibial Component. In that letter, Defendants advised customers of a change in labeling and recommended usage of the MIS Stemmed Tibial Component:

Zimmer is enhancing the labeling for the NexGen MIS Tibial Component in several important ways. The changes to the labeling include the following recommendations:

1. to achieve adequate visualization and access if an MIS approach is used,

2. to use a drop down stem extension with the NexGen MIS Tibial Component,

3. to fully cement and pressurize the anterior and posterior surfaces of the tibial component, and

4. to carefully use bone cement application per the manufacturer's instructions.

33. On September 13, 2010, the FDA classified the Defendants' efforts relating to the MIS Stemmed Tibial Component as a Class II Recall.

34. From the time that Defendants first began selling the Zimmer NexGen Knee in the United States, the product labeling and product information for the Zimmer NexGen Knee failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen Knee can loosen in patients.

35. Despite its knowledge of the serious injuries associated with using the Zimmer NexGen Knee, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that using the Zimmer NexGen Knee was safe.

36. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen Knee and through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the Zimmer NexGen Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

FACTUAL ALLEGATIONS

37. On September 9, 2006, Plaintiff's physician implanted a Zimmer NexGen Knee system including a NexGen CR High Flex femoral component and a MIS Stemmed Tibial Component.

38. Prior to September 9, 2006, the treating physician for Plaintiff, as well as Plaintiff, was exposed to the aforementioned advertising and marketing campaign directly by the Defendants.

39. Plaintiff and Plaintiff's physician, either through direct promotional contact with Defendants' sales force, through word-of-mouth from other health care providers, and/or through promotional materials, received the information the Defendants intended that they receive, to-wit: that the Zimmer NexGen Knee was safe and effective for use in TKA procedures.

40. Plaintiff began experiencing severe and debilitating pain shortly after implant.

41. Plaintiff returned to Plaintiff's physician several times due to consistent pain in his knee.

42. In 2008, Plaintiff had a second surgery to revise/replace his previously implanted Zimmer NexGen Knee because of loosening. Plaintiff's entire artificial knee system was replaced. Plaintiff was never told, by any source, that his knee failed because the product itself was defectively designed.

43. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff suffered, and continues to suffer, serious bodily injury and harm.

44. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff incurred, and continues to incur, medical expenses to treat his injuries and condition.

45. At no time material to his use of the Zimmer NexGen Knee was Plaintiff or his physicians told, warned, or given information about the higher risks of loosening in the Zimmer NexGen Knee.

COUNT I
STRICT LIABILITY

46. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

47. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Zimmer NexGen Knee. Defendants designed, manufactured, marketed, and sold Zimmer NexGen Knee to medical professionals and their patients, knowing it would be implanted for knee replacements.

48. The Zimmer NexGen Knee as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a reasonably foreseeable and intended manner.

49. The Zimmer NexGen Knee was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Zimmer NexGen Knee was in a condition not suitable for their proper and intended use among patients.

50. The Zimmer NexGen Knee was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.

51. The Zimmer NexGen Knee is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures and because it was sold without adequate warnings regarding, inter alia, the propensity of Zimmer NexGen Knee to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer NexGen Knee; and the probability of suffering loosening and revision surgery.

52. As a direct and proximate result of the Zimmer NexGen Knee's defective and dangerous design and inadequate warnings as aforesaid, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, pain and suffering, and the loss of a normal life all to Plaintiff's damages.

COUNT II
NEGLIGENCE

53. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

54. At all relevant times, Defendants had a duty to exercise reasonable care in the design, testing, manufacture, marketing, sale, and distribution of Zimmer NexGen Knee.

55. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of Zimmer NexGen Knee because Defendants knew or should have known that Zimmer NexGen Knee had a propensity to cause serious injury, including loosening and revision surgery and failed to provide adequate warnings to the implanting doctors and the general public regarding the risk of serious injury, including, loosening and revision surgery.

56. As a direct and proximate result of Defendants' acts and omissions as aforesaid, Plaintiff suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, pain and suffering, and loss of a normal life all to Plaintiff's damages.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

3. Double or triple damages as allowed by law;

4. Attorneys' fees, expenses, and costs of this action;

5. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

6. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

February 21, 2011

Respectfully submitted,

FOOTE, MEYERS, MIELKE, & FLOWERS

/S/ Peter J. Flowers
Peter J. Flowers, Esq., IL# 06210847
3 North Second Street, Suite 300
St. Charles, IL 60174
Phone: (630) 232-6333
Fax: (630) 845-8982

Email: pjf@foote-meyers.com
Local Counsel for Plaintiff

Timothy J. Becker, Esq., MN# 256663
(*pro hac vice* to be filed)
Stacy K. Hauer, Esq., MN# 317093
(*pro hac vice* to be filed)
Jason P. Johnston, Esq., MN# 0391206
(*pro hac vice* to be filed)
ZIMMERMAN REED, P.L.L.P.
1100 IDS Center
80th South 8th Street
Minneapolis, MN 55402
Phone: (612) 341-0400
Fax: (612) 341-0844
Email: timothy.becker@zimmreed.com
Email: stacy.hauer@zimmreed.com
Email: jason.johnston@zimmreed.com
Out of State Counsel for Plaintiff

Marc D. Grossman, Esq., NY# 0730
(*pro hac vice* to be filed)
Meryl Veiner, Esq.
(*pro hac vice* to be filed)
100 Herricks Road
Mineola, New York 11501
Phone: (621) 741-5252
Fax: (516) 741-1243
Email: mgrossman@thesandersfirm.com
Out of State Counsel for Plaintiff